§ 201.58

§ 201.58 Requests for waiver of requirement for adequate and well-controlled studies to substantiate certain labeling statements.

A request under §201.57(b)(2)(ii), (c)(2), (c)(3)(i), (c)(3)(v), (f)(9), and (g)(4) for a waiver of the requirements of §314.126(b) of this chapter shall be submitted in writing as provided in §314.126(b) to the Director, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20587, or, if applicable, the Director, Center for Biologics Evaluation and Research, 8800 Rockville Pike, Bethesda, MD 20892. The waiver shall be granted or denied in writing by such Director or the Director's designee.

[55 FR 11576, Mar. 29, 1990]

\$201.59 Effective date of \$\$201.56, 201.57, 201.100(d)(3), and 201.100(e).

(a) On and after December 26, 1979, no person may initially introduce or initially deliver for introduction into interstate commerce any drug to which §§ 201.56, 201.57, 201.100(d)(3) apply unless the drug's labeling complies with the requirements set forth in the regulations, with the following exceptions:

- (1) If the drug is a prescription drug that is not a biologic and not subject to section 505 of the act (21 U.S.C. 355), and was not subject to former section 507 of the act (21 U.S.C. 357, repealed 1997), §§ 201.56, 201.57, and 201.100(d)(3) are effective on April 10, 1981.
- (2) If the drug is a prescription drug that on December 26, 1979 is (i) a licensed biologic, (ii) a new drug subject to an approved new drug application or abbreviated new drug application under section 505 of the act or (iii) an antibiotic drug subject to an approved antibiotic form, §§201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.
- (3) If the drug is approved after December 26, 1979 but is a duplicate of a drug approved on or before that date (for example, a drug approved under an abbreviated new drug application or an antibiotic form), §§ 201.56, 201.57, and 201.100(d)(3) are effective on the date listed below for the class of drugs to which the drug belongs. Dates are also listed below for the submission of supplemental applications, amendments, and license changes.

| Effective | Revised label- ing due | Drug class | Mail routing code | | | |
|--------------------------------|---------------------------|---|----------------------------------|--|--|--|
| Biologics | | | | | | |
| Nov. 1, 1982 | Nov. 1, 1980 | Bacterial vaccines and antigens with no U.S. standard of potency. | HFB-240 | | | |
| Do | do | Skin test antigens | HFB-240 | | | |
| Nov. 1, 1982 ¹ | Nov. 1,1980 ² | Bacteral vaccines and toxoids with standards of potency | HFB-240 | | | |
| Do | do | Viral and rickettsial vaccines | | | | |
| Do | do | Allergenic extracts | HFB-240 | | | |
| Do | do | Blood and blood derivatives | HFB-240 | | | |
| NEW DRUGS AND ANTIBIOTIC DRUGS | | | | | | |
| Nov. 1, 1982 | Nov. 1, 1980 | Antiarrhythmics | HFD-110 | | | |
| Do | do | Replenishers and regulators of electrolytes and water balance | HFD-110, HFD-510, and HFD-160 | | | |
| Do | do | Anticonvulsants | HFD-120 | | | |
| Do | do | Adrenal corticosteroids | HFD-510 and HFD-150 | | | |
| Do | do | Aminoglycosides | HFD-520 | | | |
| Do | do | Scabicides | Do. | | | |
| Do | do | Pediculicides | Do. | | | |
| Do | do | General anesthetics | HFD-160 | | | |
| Dec. 1, 1982 | Dec. 1, 1980 | Antivirals | HFD-520 | | | |
| Do | do | Dermatologics | Do. | | | |
| Jan. 1, 1983 | Jan. 1, 1981 | Glaucoma ophthalmics | HFD-520 | | | |
| Do | do | Topical otics | Do. | | | |
| Feb. 1, 1983 | Feb. 1, 1981 | Antispasmodics | HFD-110 | | | |
| Do | do | Anticholinergics | Do. | | | |
| Do | do | Diuretics | Do. | | | |
| Do | do | Narcotic antagonists | HFD-120 | | | |
| Do | do | Alcohol antagonists | Do. | | | |

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| Do | Effective | | Drug class | Mail routing code |
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| Do. | Do | | | HFD-510 |
| DO do Antiport HFD-520 Mar 1, 1983 Mar 1, 1981 Vaginal antibiotics HFD-520 Apr 1, 1983 Mar 1, 1981 Vaginal antibiotics HFD-520 May 1, 1983 May 1, 1981 General analgesics HFD-520 Do do Herboration HFD-100 Do do Herboration HFD-520 Do do Herboration HFD-520 Do do Herboration HFD-120 Do do Hydralian phromones HFD-520 Do do Hydralian phromones HFD-50 Do do Cycloplegic ophthalmics HFD-50 Do do Radiopharmaceuticals, diagnostic HFD-160 Do do Radiopharmaceuticals, diagnostic HFD-160 Do do Actinition Do. June 1, 1883 June 1, 1883 HFD-160 July 1, 1983 July 1, 1981 Antifical Myl 1, 1981 July 1, 1984 July 1, 198 | | | | |
| DO do Antigout HFD-150 Mar. 1, 1983 Apr. 1, 1981 Apr. 1, 1983 Apr. 1, 1983 May 1, 1983 May 1, 1983 May 1, 1983 May 1, 1981 May 1, 1983 May 1, 1981 May 1, 1983 May 1, 1984 | | | | |
| Mar. 1, 1983 Mar. 1, 1981 Vaginal antibiotics HFD-520 HFD-520 May 1, 1983 May 1, 1981 Gerbalaspoprins HFD-520 HFD-120 HFD-12 | | | | |
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| May 1, 1983 | | | | |
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| Do do Hypothalamic hormones | | | | |
| Do do Progestins Do. Do do do Mydriatic ophthalmics | | | | |
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| Do | | | | |
| June 1, 1983 July 1, 1981 Antifungals HFD-510 Do | | | | |
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| Do do CNS stimulants HFD-120 Do do Anorexiants Do. Do do Chloramphenicol and derivatives HFD-520 May 1, 1984 May 1, 1982 Drugs indicated for vertigo/motion sickness/vomiting HFD-120 Do do Antidiuretics HFD-510 Do do Contraceptives Do. Do do Macrolides HFD-520 Do do Lincosamides Do. Do do Antiarthritics HFD-150 Do do Antitussives HFD-160 Do do Expectorants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | Apr. 1, 1984 | Apr. 1, 1982 | Antianginals | HFD-110 |
| Do do Anorexiants Do. Do do Chloramphenicol and derivatives HFD-520 May 1, 1984 May 1, 1982 Drugs indicated for vertigo/motion sickness/vomiting HFD-120 Do do Antidiuretics HFD-510 Do do Contraceptives Do. Do do Macrolides HFD-520 Do do Lincosamides Do. Do do Antiarthritics HFD-150 Do do Antitussives HFD-160 Do do Inhalants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | Do | | | Do. |
| Do do Chloramphenicol and derivatives HFD-520 May 1, 1984 May 1, 1982 Drugs indicated for vertigo/motion sickness/vomiting HFD-120 Do do Antidiuretics HFD-510 Do do Contraceptives Do. Do do Macrolides HFD-520 Do do Lincosamides Do. Do do Antiarthritics HFD-150 Do do Antitussives HFD-160 Do do Expectorants Do. Do do Inhalants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | Do | do | CNS stimulants | HFD-120 |
| May 1, 1984 May 1, 1982 Drugs indicated for vertigo/motion sickness/vomiting HFD-120 Do do Antidiuretics HFD-510 Do do Contraceptives Do. Do do Macrolides HFD-520 Do do Antiarthritics Do. Do do Antiarthritics HFD-150 Do do Antitussives HFD-160 Do do Expectorants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | | | | |
| Do do Antidiuretics HFD-510 Do do Contraceptives Do. Do do Macrolides HFD-520 Do do Lincosamides Do. Do do Antiarthritics HFD-150 Do do Antitussives HFD-160 Do do Expectorants Do. Do do Inhalants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | | | | |
| Do do Contraceptives Do. Do do Macrolides HFD-520 Do do Lincosamides Do. Do do Antiarthritics HFD-150 Do do Antitussives HFD-160 Do do Expectorants Do. Do do Inhalants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | | | | |
| Do do Macrolides HFD-520 Do do Lincosamides Do. Do do Antiarthritics HFD-150 Do do Antitussives HFD-160 Do do Expectorants Do. Do do Inhalants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | | | | |
| Do do Lincosamides Do. Do do Antiarthritics HFD-150 Do do Antitussives HFD-160 Do do Expectorants Do. Do do Inhalants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | | | | |
| Do do Antiarthritics HFD-150 Do do Antitussives HFD-160 Do do Expectorants Do. Do do Inhalants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | | | | _ |
| Do do Antitussives HFD-160 Do do Expectorants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | | | | |
| Dododo Expectorants Do. Dodododo Inhalants Do. June 1, 1984 June 1, 1982 Urinary tract antiseptics | | | | |
| Dododo | | | | |
| June 1, 1984 June 1, 1982 Urinary tract antiseptics HFD-520 | | | | |
| | | | | |
| | | | Chelating agents/heavy metal antagonists | |

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| Effective | Revised label- ing due | Drug class | Mail routing code |
|---------------|---------------------------|---|-------------------|
| Do | do | All other gastrointestinal drugs | HFD-110 |
| Do | do | Antianxiety | HFD-120 |
| Do | do | Drugs indicated for myasthenia gravis | HFD-120 |
| Do | do | All other antiinfective drugs | HFD-520 |
| Do | do | Bronchodilators/antiasthmatics | HFD-160 |
| Aug. 1, 1984 | Aug. 1, 1982 | Estrogens | HFD-510 |
| Do | do | Uterine stimulants | HFD-510 |
| Do | do | Uterine relaxants | Do. |
| Sept. 1, 1984 | Sept. 1, 1982 | Drugs indicated for hypotension and shock | HFD-110 |
| Oct. 1, 1984 | Oct. 1, 1982 | All other cardiac drugs | HFD-110 |
| Do | do | Nasal decongestants | HFD-160 |
| Nov. 1, 1984 | Nov. 1, 1982 | All other prescription drugs. | |

¹ Except the effective date for all biological products reviewed generically by the advisory panel is 30 months after a final order

Subpart C—Labeling Requirements for Over-the-Counter Drugs

SOURCE: 41 FR 6908, Feb. 13, 1976, unless otherwise noted.

§ 201.60 Principal display panel.

The term principal display panel, as it applies to over-the-counter drugs in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term area of the principal display panel means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

- (b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and
- (c) In the case of any other shape of container, 40 percent of the total surface of the container: Provided, however, That where such container presents an obvious "principal display panel" such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§ 201.61 Statement of identity.

- (a) The principal display panel of an over-the-counter drug in package form shall bear as one of its principal features a statement of the identity of the commodity.
- (b) Such statement of identity shall be in terms of the established name of the drug, if any there be, followed by an accurate statement of the general

is published under 21 CFR 601.25(g).

² Except the due date for all biological products reviewed generically by the advisory panel is 6 months after a final order is published under 21 CFR 601.25(g).

⁽b) Section 201.100(e) is effective April 10, 1981.

^{[45} FR 32552, May 16, 1980, as amended at 46 FR 7272, Jan. 23, 1981; 49 FR 14331, Apr. 11, 1984; 50 FR 8995, Mar. 6, 1985; 55 FR 11576, Mar. 29, 1990; 64 FR 400, Jan. 5, 1999]